OSME

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K052027

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510(k) Summary

(a) (1) Submitter's name, address

Osmetech Inc.
235 Hembree Park Drive
Roswell, GA 30076

Contact Person

Daniel R. McMinn
Vice President, Operations
770.510.4444 x 4573

Date of preparation of this summary: 25 July 2005

(2) Device trade or proprietary name: OPTI LION Electrolyte Analyzer

Device common or usual name or classification name

pH and Electrolyte analyzer

CLASSIFICATION

Product Nomenclature	Classification Number	Class	Panel
ELECTRODE, BLOOD PH	75 CHL	II	CHEMISTRY
ELECTRODE, ION SPECIFIC, SODIUM	75 JGS	II	CHEMISTRY
ELECTRODE, ION SPECIFIC, POTASSIUM	75 CEM	II	CHEMISTRY
ELECTRODE, ION SPECIFIC, IONIZED CALCIUM	75 JFP	II	CHEMISTRY
ELECTRODE, ION SPECIFIC, CHLORIDE	75 CGZ	II	CHEMISTRY

(3) Substantial Equivalence

The Osmetech OPTI LION Electrolyte Analyzer is substantially equivalent in function, safety and efficacy to a number of currently marketed devices known as 'Combi Analyzers' and 'Point of Care' analyzers, Specifically: OPTI CCA [K974784, K984299, and K852473], Roche OMNI [K945915, K990092], electrolyte analyzers such as AVL 995 [K895317] and AVL 9180 [972763] and the chemistry analyzer such as Roche Diagnostics Cobas Integra [K951595]. The OPTI LION is modified design of the OPTI Critical Care Analyzer [K974784, K984299 and K852473] to allow measurement of only electrolytes and pH. A comparison of features between the Osmetech OPTI LION Electrolyte Analyzer and a number of the above listed devices is provided under the tab, **Predicate Devices.**

(4) Description of the new device

The OPTI LION Electrolyte Analyzer is a small [4.7 x 14.2 x 9.1 inches, 10 pounds], microprocessor-based instrument using optical fluorescence for the measurement of pH, sodium, potassium, ionized calcium, and chloride and utilizes a graphical touch screen user interface.

The disposable, single use cassette contains five optical fluorescent sensors placed in a polycarbonate substrate, which is packaged with an insert-able sample probe

into a sealed foil pouch which bears a bar-code label with calibration, lot identification, and expiration dating information.

(5) Intended use of the device

The Osmetech OPTI LION Electrolyte Analyzer is intended to be used for the measurement of pH, sodium, potassium, ionized calcium, and chloride in samples of whole blood, serum, plasma and aqueous controls in either a traditional clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results.

(6) Technological characteristics of the device

Principles of Measurement

The OPTI LION uses fluorescence optode to measure the intensity of light emitted from fluorescent dyes exposed to a specific analyte. The principle of measurement is similar to that used in OPTI CCA [K974784, K984299, and K852473]. The concentration of the analyte is determined by the calculation of the different in fluorescence measured at a defined calibration point and that measured with the unknown concentration of analyte.

Calibration

Each lot of OPTI LION cassettes is calibrated during the manufacturing process. Every cassette package has a barcode label containing this calibration information as well as its lot number and expiration date.

The OPTI LION system uses a proprietary dry calibration process based on the simple well-defined relationship of fluorescent intensity in the sensor's dry state to that in the sensor's mid-physiologic wet state, that is, the fluorescent intensity at mid-physiologic analyte levels. This dry-to-wet (mid-physiologic) relationship is stable and consistent for all sensors in a lot, and is characterized and bar-coded at the factory. In addition, the sensor's wet response curve of the fluorescent intensity versus analyte level is factory-characterized and bar-coded; similar to the proven method employed in the OPTI CCA analyzer.

Prior to running a sample, the cassette's bar code is read into the analyzer by 'swiping' the cassette package through a conveniently located bar code reader. The cassette is then installed and a calibration is performed. In addition, an optical zero point calibration of all optical channels is performed.

During the calibration and measurement processes, diagnostic tests are automatically performed to assure correct operation of the instrument and measurement of the cassette. These tests include automatic checks of the cassette for packaging integrity, proper cassette temperature control, and proper equilibration behavior of the sensors during calibration and measurement,

automatic detection of bubbles and short sample during aspiration, automatic detection of dirty optics.

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

Performance Standards

The Osmetech OPTI LION Electrolyte Analyzer has been tested and found to comply with EN61010-1, FCC Class B, EN55022, EN61000-3-2, EN61000-3-3, and EN61326-1.

Precision[1]

The precision study was carried out following the experimental protocol recommended in the NCCLS guideline EP5-A, volume 19, Number 2 (1999). Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) precision were determined from two runs per day over 20 days on two OPTI LION instruments in simulated low- and high-use tests using three levels of aqueous quality control solution.

Linearity[2]

The precision study was carried out following the polynomial method recommended in the NCCLS guideline EP6-A, volume 23, Number 16 (2003). Wherever possible, linearity for the OPTI LION measurement has been established against reference materials or methods. Linearity for pH of plasma and whole blood are established by measurement of plasma and whole specimens which were tonometered to seven pH levels with various CO2 values, and measured on an AVL 995 and AVL 9181 pH/Blood Gas Analyzer standardized to N.I.S.T. traceable pH buffers, and on OPTI LION Analyzers.

Interferences[3]

Extensive testing for potential interferents has been carried out for OPTI CCA 510(k) interference study and has identified interferents which can affect the performance of the sodium, potassium, calcium, chloride and pH sensors in OPTI LION. Since the dry calibration is not affected by the interferent and the wet fluorophore is the same, we do not expect new sensitivities. Representative interference substances were evaluated following the NCCLS guideline.

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[1] NCCLS Approved Guideline, EP5-A, volume 19, Number 2, 1999: Evaluation of Precision Performance of Clinical chemistry Devices.

[2] NCCLS Approved Guideline, EP6-A, volume 23, Number 16, 2003: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach.

[3] NCCLS Approved Guideline, EP7-A, volume 22, Number 27, 2002: Interference Testing in Clinical Chemistry.

(b) (2) Summary of clinical tests submitted with the premarket notification for the device[4].

Clinical testing was conducted to demonstrate the correlation of Osmetech OPTI LION Electrolyte Analyzer to predicate devices in a clinical setting, operated by personnel trained to perform and report these analyses. Specimens analyzed in these tests were remnant from patient specimens of both whole blood and plasma or serum collected for routine analysis on existing instrumentation.

In all evaluations, the predicted systematic differences and their 95% confidence intervals between the OPTI LION and the predicated devices for each test at medical decision levels are lower than the medically allowable errors as defined in CLIA'88 performance standards[5]

(b) (3) Conclusions drawn from the clinical and non-clinical trials.

Analysis of the method comparison data collected during clinical trials for this device presented in the 510(k), together with the linearity and precision data collected during non-clinical trials demonstrates that the Osmetech OPTI LION is safe, effective, and equivalent to those predicate devices to which it is compared.

[4] NCCLS Approved Guideline-Second Edition, EP9-A2, volume 22, Number 19, 2002: Method Comparison and Bias Estimation Using Patient Samples.

[5] Clinical Laboratory Improvements Amendments of 1988. Final Rule. Laboratory Requirements. Federal Register, February 28, 57:7002-7288, 1992.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 29 2005

Mr. Daniel R. McMinn
Vice President, Operations
Osmetech, Inc.
235 Hembree Park Drive
Roswell, GA 30076

Re: k052027
Trade/Device Name: Osmetech OPI LION Electrolyte Analyzer
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO_2, PO_2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL, JGS, CEM, JFP, CGZ, JJE
Dated: July 25, 2005
Received: July 27, 2005

Dear Mr. McMinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k052027

Device Name: Osmetech OPTI LION Electrolyte Analyzer

The Osmetech OPTI LION Electrolyte Analyzer is intended to be used for the measurement of sodium, potassium, chloride, ionized calcium and pH in samples of whole blood, serum and plasma as appropriate in either a traditional clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results.

For Professional Use Only
For *In Vitro* Diagnostic Use

Indications for Use

Sodium

Sodium is the major cation of extracellular fluid. Its primary functions in the body are to chemically maintain osmotic pressure and acid-base balance and to transmit nerve impulses. Sodium functions at the cell membrane level by creating an electrical potential between different cell membranes causing the transmission of nerve impulses and neuromuscular excitability to be maintained. Sodium is involved in some enzyme catalyzed reactions as a cofactor. The body has a strong tendency to maintain a total base content, and only slight changes are found even under pathologic conditions.

Low sodium values, *hyponatremia*, usually reflect a relative excess of body water rather than a low total body sodium. Reduced sodium levels may be associated with: low sodium intake; sodium losses due to vomiting or diarrhea with adequate water and inadequate salt replacement, diuretics abuse, or salt-losing nephropathy; osmotic diuresis, metabolic acidosis; adreocortical insufficiency; congenital adrenal hyperplasia; dilution type due to edema, cardiac failure, hepatic failure; and hypothyroidism.

Elevated sodium values, *hypernatremia*, are associated with conditions with water loss in excess of salt loss through profuse sweating, prolonged hyperpnea, severe vomiting or diarrhea, diabetes insipidus or diabetic acidosis; increased renal sodium conservation in hyperaldosteronism, Cushing's syndrome; inadequate water intake because of coma or hypothalamic diseases; dehydration; or excessive saline therapy.

The sodium value obtained may be used in the diagnosis or monitoring of all disturbances of the water balance, infusion therapies, vomiting, diarrhea, burns,

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heart and kidney insufficiencies, central or renal diabetes insipidus, endocrine disturbances and primary or secondary cortex insufficiency of the adrenal gland or other diseases involving electrolyte imbalance.

Potassium

Potassium is the major cation in the intracellular fluid and functions as the primary buffer within the cell itself. Ninety percent of potassium is concentrated within the cell, and damaged cells release potassium into the blood. Potassium plays an important role in nerve conduction, muscle function, and helps maintain acid-base balance and osmotic pressure.

Elevated potassium levels, *hyperkalemia*, can be found in oligouria, anemia, urinary obstruction, renal failure due to nephritis or shock, metabolic or respiratory acidosis, renal tubular acidosis with the K^+/H^+ exchange and hemolysis of the blood. Low potassium levels, *hypokalemia*, can be found in excessive loss of potassium through diarrhea or vomiting, inadequate intake of potassium, malabsorption, severe burns and increased secretion of aldosterone. High or low potassium levels may cause changes in muscle irritability, respiration and myocardial function.

The potassium value obtained may be used to monitor electrolyte imbalance in the diagnosis and treatment of infusion therapies, shock, heart or circulatory insufficiency, acid-base imbalance, therapy with diuretics, all kinds of kidney problems, diarrhea and hyper- and hypo-function of adrenal cortex and other diseases involving electrolyte imbalance.

Chloride

Chloride is an anion that exists predominantly in extracellular spaces. It maintains cellular integrity through its influence on osmotic pressure. It is also significant in monitoring acid-base balance and water balance. In metabolic acidosis, there is a reciprocal rise in chloride concentration when the bicarbonate concentration drops.

Decreased levels are found in severe vomiting, severe diarrhea, ulcerative colitis, pyloric obstruction, severe burns, heat exhaustion, diabetic acidosis, Addison's disease, fever and acute infections such as pneumonia.

Increased levels are found in dehydration, Cushing's syndrome, hyperventilation, eclampsia, anemia and cardiac decompensation.

Ionized Calcium

Calcium in blood is distributed as free calcium ions (50%) bound to protein, mostly albumin (40%) and 10% bound to anions such as bicarbonate, citrate, phosphate and lactate. However, only ionized calcium can be used by the body

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in such vital processes as muscular contraction, cardiac function, transmission of nerve impulses and blood clotting. The OPTI LION measures the ionized portion of the total calcium. In certain disorders such as pancreatitis and hyperparathyroidism, ionized calcium is a better indicator for diagnosis than total calcium.

Elevated calcium, hypercalcemia, is found in patients with increased intestinal absorption, increased mobilization from bone (osteolysis), decreased renal elimination, hyperparathyroidism and Addison's disease. Hypercalcemia may also be present in various types of malignancy, and calcium measurements may serve as biochemical markers. In general, while ionized calcium may be slightly more sensitive, either ionized or total calcium measurements have about equal utility in the detection of occult malignancy. Hypercalcemia occurs commonly in critically ill patients with abnormalities in acid-base regulation and losses of protein and albumin, which gives a clear advantage to monitoring calcium status by ionized calcium measurements.

Decreased calcium, hypocalcemia, is found in patients with decreased intestinal absorption, increased renal elimination, increased deposition of Calcium in the bones, increased binding to proteins when the pH increases or binding to citrate, and hypoparathyroidism.

Patients with renal disease caused by glomular failure often have altered concentrations of calcium, phosphate, albumin, magnesium and pH. Since these conditions tend to change ionized calcium independently of total calcium, ionized calcium is the preferred method of accurately monitoring calcium status in renal disease.

Ionized calcium is important for diagnosis or monitoring of: hypertension management, parathyroidism, renal diseases, malnutrition, kidney stones, multiple myeloma and diabetes mellitus.

Ionized calcium may be reported either as the actual ionized calcium, referred to actual pH of the patients, or as normalized ionized calcium, to a standard pH at pH 7.40. The binding of calcium by protein and small anions is influenced by pH and because of this relationship specimens should be analyzed at the pH of the patient's blood.

For more detailed information about the preanalytical variables affecting ionized calcium, please refer to the most current edition of NCCLS document C31-Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling.

pH

The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

- primary bicarbonate deficit metabolic acidosis
- primary bicarbonate excess metabolic alkalosis
- primary hypoventilation respiratory acidosis
- primary hyperventilation respiratory alkalosis

An increase in blood, serum or plasma pH, *alkalemia,* may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of CO_2 due to hyperventilation.

A decrease of pH value, *academia,* in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of H^+-ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute, as the result of pulmonary edema, airway obstruction or medication, or maybe be chronic, as the result of obstructive or restrictive respiratory diseases.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Office of In Vitro Diagnostic Device Evaluation and Safety

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